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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/11/2002

73

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/402,680

Applicant(s)
Schwarz et al.

Examiner
Michele Flood

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 16, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-75 is/are pending in the application.
- 4a) Of the above, claim(s) 65-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-49, 51-64 and 74 is/are rejected.
- 7) ☒ Claim(s) 50, 73, and 75 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

Request for Continued Examination

Election/Restriction

Applicant's election with traverse of Group I, Claims 43-64 and 73-75, in Paper No. 21 is acknowledged. The traversal is on the grounds that the claims of Group I recite the use of an alkyl phosphate free solution and that the claims of Group II recite the use of a solution that may contain alkyl phosphates. Applicant further argues that the detergent recited in Group II is also a phosphate free solution, and that the search for the recited detergents would not be unduly burdensome. This is not found persuasive because Groups I and II are directed to two different inventions, which require different ingredients and different process steps. For example, the method claim of Invention II would not necessarily be free of other alkyl phosphates since the recited limitation reads "incubating said carrier having said activated prothrombin complex adsorbed thereon in the presence of a tri-n-butyl phosphate (TNBP)-free TWEEN®-80 solution", whereas the method claims of Invention I restrict the incubation process in the presence of alkyl phosphate solutions. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group; and, thus the search and burden are substantial and not limited or encompassed by the search for the recited detergents.

The requirement is still deemed proper and is therefore made FINAL.

Claims 43-64 and 73-75 are under examination.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43-62 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide prior support or antecedent basis for the language "stabilizing a biological material on a solid carrier" in claims 43 and 62.

The claims as set forth in the amendment filed August 8, 2001, now recite a method for inactivating microorganisms and pyrogens present in biological materials comprising: "stabilizing a biological material on a solid carrier". However, nowhere in the specification does Applicant provide literal support for the meaning of "stabilizing a biological material on a solid carrier" or the means by which the claimed functional effect of stabilization of a biological material on a solid carrier is obtained. The specification as originally filed provides only for a method for inactivating microorganisms and pyrogens present in biological materials comprising a process step of adsorbing a biological material onto a solid carrier.

Insertion of the above mentioned claim limitations have no support in the as-filed specification. The insertion of the limitations is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of "stabilizing a biological material on a solid carrier". Since there is no written description to provide an interpretation of the meaning of the claim limitation, the meaning of the limitation is

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deemed confusing, vague and indefinite. Thus, for the purposes of examination the Office will interpret the meaning of "stabilizing a biological material on a solid carrier" as "adsorbing a biological material on[to] a solid carrier".

As the above mentioned claim limitations could not be found in the present specification, the recitation of the claim limitations are deemed new matter; and, therefore they must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

This is a new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43, 50, 55, 56 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to Claim 50, line 1, there is an obvious typographical error: "in". It appears that Applicant meant to type is. Appropriate correction is required, if this assumption is true.

With regard to Claims 55 and 56, Applicant should place the word said after "wherein" to place the claim in proper form.

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Regarding Claim 64, the phrases “such that” and “so as” render the claim indefinite because it is unclear whether the limitations following the phrases are part of the claimed invention.

Regarding Claim 64, line 9, no conjunction appears between the “incubating” step and “separating” step, and thus it is unclear as to whether the subject matter of the claimed invention includes the recited “separating” step. Applicant may overcome the rejection by placing and after the semicolon “;” in line 9.

All other claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Objections

Claim 50 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 50 is improperly dependent upon independent Claim 43 because the solution used in the method of microbial inactivation is free of any and all alkyl phosphate detergents, and not just tri-n-butyl phosphate (TNBP). Therefore, Claim 50 is broader in concept than Claim 43, and outside the scope of the claimed invention.

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Claims 73 and 75 are objected to, as being improperly dependent upon canceled Claim 1. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 43-52 and 55-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandra et al. (A, US 4,673,733).

Applicant claims a method for inactivating microorganisms and pyrogens present in biological materials comprising: stabilizing a biological material on a solid carrier, incubating said biological material in the presence of an alkyl phosphate-free detergent solution, said detergent solution containing at least one eluotropic salt in a total concentration of at least 200 mM; and eluting said biological material from said detergent solution. Applicant further claims a method for inactivating microorganisms and pyrogens present in biological materials comprising: stabilizing a biological material on a solid carrier, incubating said biological material

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in the presence of an alkyl phosphate-free detergent solution, said detergent solution containing at least one eluotropic salt in a total concentration of at least 200 mM; and eluting said biological material from said detergent solution; and purifying said biological material eluted from said detergent solution.

Chandra teaches a method for inactivating microorganisms and pyrogens present in biological materials comprising the steps of adsorbing the biological material onto a solid phase; treating the adsorbed product with a virus or pyrogen inactivating agent; separating the solid phase and removing the residual inactivating agent; and recovering the product. The method Chandra' method can be applied to various biomedical materials, e.g., blood protein fractions and blood factors, which are adsorbed onto a solid carrier, such as an ion exchanger and resins used for affinity chromatography, etc. See Column, lines 22-68 to Column 3, lines 1-27. In Column 2, lines 28-68 to Column 4, lines 1-60, Chandra teaches non-ionic detergents, such as polyoxyethylene ether detergents, as inactivating agents which are present in amounts of from 0.1 to 50%, 0.5%-20%, or 1-10% based on the volume of the product. The incubation time taught by Chandra is generally in the range of 1 to 10 hours. In Column 9, lines 6-24, under "EXAMPLE 5", Chandra expressly teaches the claimed invention to obtain a purified Antithrombin III preparation. The reference anticipates the claimed subject matter.

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Claims 43-48, 50-55, 57-60, 62-64 and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al. (B or O).

Evans (US Patent 5,989,421) teaches a method for the extraction of DNA from a suspension of cells, comprising the steps of 1) supplying a suspension of cells to a filter apparatus, 2) if necessary, filtering off medium in which the cells are suspended, 3) applying a lysis solution to the cells and incubating the cells for a period sufficient to release DNA therefrom; and 4) filtering off lysis solution containing DNA. Other embodiments of the method taught by Evans include; 5) applying the filtrate from step (4) to an ion-exchange medium; 6) washing the ion-exchange medium with a first solution to elute material other than DNA; and 7) washing the ion-exchange medium with a solution to elute the DNA. In Column 2, lines 20-24, Evans teaches that the method can be directed to a culture of animal cells or body fluids, such as blood. In Column 4, lines 32-62, Evans teaches incubation of cells in the presence of a lysis solution for a period of 3 to 15 minutes, wherein the lysis solution 4 M guanidine thiocyanate, 0.1 m sodium acetate, 5% Triton X-100™, and 3 M urea. Other chaotropic agents, which can be used in the method taught by Evans include guanidine hydrochloride, sodium iodide, sodium perchlorate and salts of guanidine such as guanidine thiocyanate. Evans teaches other non-ionic detergents, such as Tween™, can be used in his method. See Column 4, lines 32-47. In Column 5, lines 3-8, Evans teaches that the procedure for the lysis of the cells can be repeated several times to increase the yield of DNA. Purification of the biological material is carried out by ion exchange media such as DEAE, see Column 5, lines 9-18. In Column 10, lines 61-67 bridging

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Column 11, lines 1-58, Evans teaches a method for the extraction and purification of genomic DNA from blood comprising the steps of reacting a blood solution with a solid carrier such that the blood was adsorbed onto the solid carrier, and incubating the adsorbed blood solution with a lysis solution comprising 4 M guanidine thiocyanate, 5% Triton X-100™, 0.1 M sodium acetate and urea at concentrations from 0.5 to 4 M, followed by the elution of DNA from the nuclei of the cells. Evans does not expressly teach a method for inactivating microorganisms and pyrogens present in biological materials, however, the process steps, the ingredients used, the materials to be treated, and the experimental parameters and conditions taught by Evans are the same or essentially the same as disclosed in the claimed invention. Thus, the result would be the same or essentially the same result as disclosed in the instant application. Moreover, the lytic solution taught in the method of Evans lyses the cells of microorganisms, and comprises denaturing solvents and detergents which are well known in the art to inactivate microorganisms, pyrogens, and viruses. The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 64 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Chandra et al. (A).

Applicant claims a method for inactivating microorganisms and pyrogens present in biological materials comprising: reacting a mixture containing said biological material with a solid carrier such that said biological material is adsorbed onto said solid carrier; eluting said biological material from said solid carrier so as to create a purified biological material; incubating said purified biological material in the presence of an alkyl phosphate-free detergent solution, said detergent solution containing at least one elutrophic salt in a total concentration of at least 200 mM; separating said purified biological material from said detergent solution.

Applicant further claims a preparation according to claim 64.

The method of Chandra is set forth above. Chandra does not teach a method for microbial and pyrogen inactivation and purification of a biological material, wherein the incubation of the eluted fraction in an alkyl-phosphate free detergent elutrophic salt containing solution is effected immediately after elution of the biological material. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the referenced teaching by reversing the order of elution and incubation process steps as taught by Chandra because the order in which the process steps take place is not a critical feature of the process and will not effect the result product. Thus, the claimed invention is nothing more than the reversed steps in the making of the preparations taught by Chandra. One of ordinary skill in the art at the time the invention was made would have been motivated to modify the Chandra

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method because it would have been prima facie obvious to reverse the steps, as the claimed invention is nothing more than an arbitrary matter of experimental design choice in the making of a biological preparation.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

MCF

January 9, 2002



CHRISTOPHER R. TATE
PRIMARY EXAMINER